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COMMENTARY

The Case of Penny Wise but Access and Quality of Care Foolish

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Recently, the Healthcare Common Procedure Coding System (HCPCS) coding committee for supplies [headed up by Center for Medicare and Medicaid Services (CMS), with private payer representatives] denied a request for a unique HCPCS level II code for use of a novel bone marrow biopsy system in the physician office setting (POS). This code would in effect allow access/use of a powered bone marrow biopsy system (brand name OnControl®) in this setting, where a significant number of bone marrow biopsy procedures are performed. Hematologists and oncologists perform the vast majority of these types of procedures [1]. In randomized controlled trials this new system has demonstrated significant reductions in patient pain as well as significantly improving upon the sample yield to more accurately assess a patient's pathology [2]. It also demonstrated the potential ability for a patient to be able to better tolerate the pain of the biopsy based on the visual analog scale (VAS) pain reduction seen with the powered system [3]. Interestingly, 3 years prior to this, CMS granted a unique code for the use of OnControl® in the hospital outpatient setting (HOPS), permitting the full amount of this technology to be paid for. Why would CMS pay additionally in one care setting but deny access in another less expensive care setting (i.e., POS)? Before this question is answered, we need a history of how this determination was made.

CMS has a decision tree that it uses in determining whether a product/service should be granted a unique HCPCS code [4]. According to CMS representatives, this request for a new code answered every one of the decision tree points (including strong support from lymphoma patient advocacy groups for its use based on less pain and improved outcomes) in the affirmative, save one: that this technology belongs in a different code set, namely Common Procedure Terminology (CPT) level 1 coding [4]. A unique CPT code had been applied for through the American Medical Association (AMA) CPT back in 2011. As part of the application process, the AMA CPT editorial panel provides feedback to the applicant. The feedback provided by medical specialties such as the American Society of Hematology (ASH) and the American Society of Clinical Oncology (ASCO) stated that a CPT code already existed (CPT 38221—bone marrow biopsy, needle or trocar) and that the AMA only established codes for services, not technologies.

Currently CPT 38221 is paid by CMS at a national average rate of US$170.19 in the POS. This payment includes the cost of a manual biopsy needle at an amount of US$34.47—an inferior system to OnControl® (based on outcomes). Unfortunately, OnControl®, has a list price of US$140. Thus, if a clinician were to use OnControl® in the POS, they would likely lose money considering the other costs that are incurred in this setting include physician labor, other clinical labor, and other supplies associated with this procedure. Therefore, the CMS payment of US$170.19 effectively prohibits access of OnControl® in the POS. An alternative presented back in 2013 to ASCO and ASH was to "re-price" CPT 38221 to include the costs of OnControl®. The problem with this option is that if CPT 38221 were "re-priced", it would incentivize clinicians to use the manual needle system instead of OnControl® and "pocket" the difference. ASCO representatives suggested that a unique HCPCS level II code was a reasonable path to follow. An application and presentation was made to CMS on 28 May 2014, with the hope of establishing a unique

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HCPCS level II for the POS—to be used in conjunction with CPT 38221. Unfortunately, CMS came back with the determination that coding for this is the AMA's responsibility and not theirs. This effectively restricted access (based on inadequate payment) to the use OnControl® only in the HOPS. What is so bad about having adequate payment for OnControl® in the HOPS only?

In addressing this question, here are the issues with having access to only one care setting (HOPS): first, it costs the healthcare system significantly more to provide the same procedure in the HOPS versus the POS. Even if OnControl® were to be paid additionally in the POS [HOPS pays US$910 vs. POS at US$276 (US$170 + US$106; assumes that OnControl® would be paid at the differential of its list price of US$140 less an existing payment of US$34 for the manual biopsy system)], POS would be significantly less costly. Second, not every patient has access to HOPS, some only have access to the POS. Third, it denies access to better medicine, as noted above.

Why would CMS allow for access for this product (based on coding and payment) in one care setting and not another? Perhaps it has to do with more clinicians using OnControl® in the POS and its cost. Current estimates are that approximately 43 % of all bone marrow biopsies are performed in the POS. For CMS, this amounts to 61,000 bone marrow procedures performed in the POS for the 2012 fiscal year [1]. If a unique HCPCS level II code were established (and assuming all of these procedures were now performed using OnControl®), it would amount to an additional US$6.5 million to CMS. Considering CMS's budget is US$525 billion, this amounts to a 0.001 % increase in their budget—in essence a rounding error. Perhaps it has to do with the HCPCS coding committee setting a precedent in establishing a unique HCPCS code. In the presentation made to the committee on 28 May 2014, numerous examples were provided where CMS had established unique HCPCS codes that were the responsibility of the AMA CPT panel [5]. What is it then? The only conclusion that this author can come up with is that CMS is being penny wise but access and quality of care foolish. As it relates to the US's triple aim [improving health outcomes, enhancing the patient experience (including access), and controlling/reducing per capita costs of health care] [6], the decision made by CMS has achieved a singular aim in ensuring care is less costly. However, improving the experience and outcomes were apparently not considered in this decision. CMS's mission is as follows: "as an effective steward of public funds, CMS is committed to strengthening and modernizing the nation's health care system to provide access to high quality care and improved health at lower cost". Again, the CMS apparently did not consider its mission in this decision.

So whose responsibility should it be to ensure that OnControl® is accessible? It is this author's contention that the responsibility for establishing a HCPCS code and in pricing it lies with the provider and payer communities, since they are using and paying for it. CMS's abdicating this responsibility to others is avoiding a decision that they should be making (and for which they have done so in the past) and goes against their mission. Providers abdicating this responsibility goes against ensuring their patients have access to high-quality care. Thus, access to high-quality care is held in limbo, stuck between two entities (payers and providers) who are saying in effect, "This is your responsibility, not mine".

Is it also the author's opinion that the Affordable Care Act has resulted in decision makers (i.e., CMS, private payers, hematology/oncology) becoming gun shy over any kind of novel medical technology that even hints at an increase in costs to the system. As noted in the Strategic Goal #1 for strengthening healthcare located on the Department of Health and Human Services website [7], there is no mention anywhere in the objectives listed for increasing costs, only in either keeping them the same (and improving quality) or in lowering them and improving quality. This is currently how value is being defined in the USA. Based on the pressure that decision makers are under to decrease costs, it is not surprising that this technology was not granted an HCPCS code. Decision makers are thus being encouraged to pay for value if it results in the same or lower costs. This in itself is extremely concerning.

Ultimately, how does this affect the medical community? This may just be the tip of the iceberg regarding CMS determinations that follow. CMS has effectively drawn a line in the sand stating it will not pay additionally for value. This may result in other more costly care that provides for better quality and access also being denied. Is this a harbinger for things to come, and is this what the medical community and patients want? Paying more for value should also be part of the purchase equation in healthcare as it commonly is in all other parts of commerce.

What is needed are alternative methodologies that define value that is created. A way to do so is by examining the downstream effects of a false negative finding with a manual biopsy (i.e., for lymphoma). Below is what this might look like.

For the cost differential:

- CMS currently pays US$170.19 (national average) for CPT 38221 (bone marrow biopsy) when this procedure is performed in the POS. Embedded in this amount is US$34.47 allocated for manual bone marrow biopsy supplies. As a side note, if the same procedure were performed in the HOPS (approximately 57 % are performed in this setting), the CMS reimbursement is

currently US$826.26 (hospital) + US$84.37 (physician) = US$910.63.

- Assume that CMS were to pay for OnControl® in the POS at the differential in supply costs between OnControl® and the manual biopsy needle costs embedded in CPT 38221, or US$140−US$34.47 = US$105.53. Thus, the total CMS reimbursement for use of the powered biopsy procedure would be US$105.53 + US$170.19 = US$275.72.

For outcomes:

- A significantly longer trephine biopsy length (i.e., biopsy sample) with OnControl® [2]. In a recent study, this increased trephine length was shown to increase the positivity for lymphoma diagnosis by 25 % [65.5 % positivity with a trephine length of 13–16 mm (OnControl® finding) vs. 40.7 % positivity with a trephine length of 9–12 mm (manual biopsy finding)] [2, 8]. In other words, the samples provided with OnControl® reduced the number of false negative findings for lymphoma diagnosis (false negative = a negative diagnostic finding when in fact lymphoma was present).
- For the cost analysis, let's assume based on above that one in four lymphomas will be missed based on a 25 % differential in sensitivity between powered and manual biopsy [8].

Based on current National Comprehensive Cancer Network (NCCN) guidelines, a bone marrow biopsy may be considered adequate if it is diagnostic for lymphoma [9]. If the manual biopsy result is not diagnostic and lymphoma is suspected, a patient will likely undergo follow-on contrast-enhanced computed tomography (CT) scans of the neck/chest/abdomen/pelvis (a total of three would be performed) [9]. At current CMS rates and with multiple procedure discounts, this results in an additional cost of US$744.60.

Using TreeAge Software, these costs were modeled out. In the case where a false negative occurs on biopsy and the clinician is smart enough to suspect lymphoma (and thus order a CT scan), the costs of a false negative (which is a portion of all biopsy costs) equals US$356.34 (manual biopsy at US$170.19 + contrast-enhanced CT scans of the neck, chest, and abdomen/pelvis regions at US$744.60 × 0.25) versus OnControl® at US$275.72. Thus, in the case of a false negative finding on manual biopsy for lymphoma, OnControl® costs less. Again, since trephine sizes are smaller with a manual biopsy (and smaller trephine sizes result in a higher proportion of false negatives), these types of situations likely occur more frequently than realized [8].

While new technologies that increase costs and improve value are likely to be denied by payers prima facie, additional analysis such as the above may help. Until this happens, newer, slightly more expensive technologies/services will likely be denied.

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